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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,746	07/26/2001	Yajun Guo		1834

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EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
07/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/915,746	GUO ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *23 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *6 and 18* is/are allowed.

6)☐ Claim(s) *1,4 and 7-17* is/are rejected.

7)☐ Claim(s) *2,3 and 5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 7 and 18 have been amended. Claims 1-18 are pending and under consideration.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 7, 8-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 7 is drawn to an antigen, characterized in that said antigen is specifically bound by the monoclonal antibody produced by the hybridoma deposited under ATCC Accession No. HB-12588, and wherein said antigen is present on the membrane and in the cytoplasm of human melanoma cells but not present in normal, non-activated human melanocytic cells and non-melanocytic human tumor cells in an amount which is detectable by said monoclonal antibody. Thus, the claimed antigen is characterized only by functional attributes, (binding to the antibody, and presence on the surface of a specific cell type) because the structure of the epitope bound by said antibody cannot be inferred from the deposited hybridoma, and the epitope may in fact be a three dimensional epitope not dependent on a linear peptide sequence.

Claims 1 and 4 are drawn to monoclonal antibodies which specifically bind to the above antigen, and hybridomas thereof. It is noted that claim 1 does not require that the claimed antibodies specifically inhibit the binding of the monoclonal antibody produced by the deposited hybridoma, HB-12588, and thus the claims read on monoclonal antibodies which bind to different epitopes than that bound by the antibody produced by the deposited hybridoma,

Claims 8-17 are method claims reliant on the identity of the antigen characterized only by binding to the monoclonal antibody produced by the deposited hybridoma, and the expression pattern of the antigen, as stated above.

The instant claims lack adequate written description because the antigen to which the antibodies bind, lacks adequate written description. The characterization of said antigen relies only on the functional attributes of the antigen, without related these functional attributes to structural requirements. when given the broadest reasonable interpretation, the term "antigen" can encompass a polypeptide which comprises, rather than consists of an antibody binding site and therefore the term antigen can include proteins which are bound by antibodies.

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

In the instant case, the antibody of claim 1 can bind to an antibody binding site on an epitope which is accessible to antibody-binding, but is not limited to binding to the epitope of the antibody secreted by the hybridoma HB-12588. The specification fails to describe the complete protein encompassing the epitope bound by the HB-12588 antibody, or alternate epitopes which are part of the same protein, but sterically separated. therefore the description of the HB-12588

binding to an epitope of melanoma cells fails to adequately describe the protein, or other epitopes which are part of the same protein. Because the full protein is not described it logically follows that other antibodies which bind to non-related antibody epitopes on the "antigen" are also not described. thus methods of claims 1 and 9 which rely on the identity of the antigen by means of qualifying specific binding to HB-12588 are inadequately described because an antigen can be interpreted to encompass an entire protein. It is noted that claim 2 is adequately described because an antibody which competitively inhibits the HB-12588 antibody is binding to the same, or nearly the same epitope as HB-125888.

Applicant argues that the instant specification adequately described the presently claimed subject matter because it is disclosed that the antigen is present on the membrane and the cytoplasm of human melanoma cells, but is not detectable in normal non-activated human melanocytic cells. Applicant further argues tat the antigen was immunoprecipitated from cell extracts and has an apparent molecular weight of 200kD. This has been considered but not found persuasive. As stated above, adequate written description requires a precise definition of chemical structure or a combination of chemical structure and function that could be used to discern the inventive antigen from other antigens. the presence of the antigen on melanoma cells and the apparent molecular weight do not constitute exact chemical structures. further disclosing a method for identifying the antigen bound by the antibody is not commensurate with a description of said antigen.

Claims 2, 3 and 5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 6 and 18 are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Trefzer et al (BMC Cancer, 2006, vol. 6, pp. 1-12) disclose some partial characteristic of the fibronectin variant bound by the SN5-1 antibody.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A. Canella?
Ph.D., Primary Examiner

Art Unit 1643